

## **REMARKS**

This amendment and these remarks are responsive to the non-final Office action dated June 1, 2005, and are being submitted under 37 C.F.R. § 1.111. Claims 1-24 and 39-53 are pending in the application. In the Office action, the Examiner (1) objected to claims 5, 8-11, 21-23, 44, and 47-50 (as being dependent upon a rejected based claim); and (2) rejected claims 1-4, 6, 7, 12-20, 24, 39-43, 45, 46, and 51-53 as follows:

- Claims 1-4, 6, 7, 13-14, 16, 18-20, 40-43, 45, 46, 52, and 53 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,658,283 to Huebner ("Huebner");
- Claims 13 and 16 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,053,915 to Bruchmann ("Bruchmann") and by U.S. Patent No. 3,488,779 to Christensen ("Christensen");
- Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Christensen in view of U.S. Patent No. 6,096,040 to Esser ("Esser"); and
- Claims 1-4, 6-7, 12-20, 24, 39-43, 45, 46, and 51-53 were rejected provisionally for obviousness-type double patenting over claim 4 or claim 7 of copending U.S. Patent Application Serial No. 10/717,399 ('399) in view of Huebner.

Applicants traverse the rejections, contending that rejected claims 1-4, 6, 7, 12-20, 24, 39-43, 45, 46, and 51-53 are neither anticipated nor obvious. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants would like to patent now, applicants have amended claims 1, 13, 15, 18, and 40, and have canceled claim 39. Applicants reserve the right to pursue claim 39, in original or amended form, at a later time. Furthermore, applicants have presented arguments showing that claims 1-24 and 40-53 are neither taught nor suggested by any of the references of record. Accordingly, applicants

respectfully request reconsideration of the rejected claims, and prompt issuance of a Notice of Allowability covering all of the pending claims.

***I. Information Disclosure Statement***

Applicants will be submitting a supplemental Information Disclosure Statement (IDS) for this application soon, and respectfully ask the Examiner to consider the IDS, and the references cited therein, in reviewing this communication.

***II. Interview with the Examiner***

Applicants' agent, Stan Hollenberg (Reg. No. 47,658), participated in a telephone interview with the Examiner on July 13, 2005. Potential amendments to claim 1 were discussed but agreement was not reached.

***III. Claim Rejections – 35 U.S.C. §§ 102 and 103***

The Examiner rejected claims 1-4, 6, 7, 13, 14, 16, 18-20, 40-43, 45, 46, 52, and 53 under 35 U.S.C. § 102(b) as being anticipated by Huebner, claims 13 and 16 as being anticipated by Bruchmann and by Christensen, and claim 15 as being obvious over Christensen in view of Esser. Applicants traverse these rejections. None of these references, either alone or in combination, teaches or suggests each of the elements of any of these claims. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants would like to patent now, applicants have amended claims 1, 13, 15, 18, and 40. Applicants reserve the right to pursue original and/or previously amended forms of these claims at a later time.

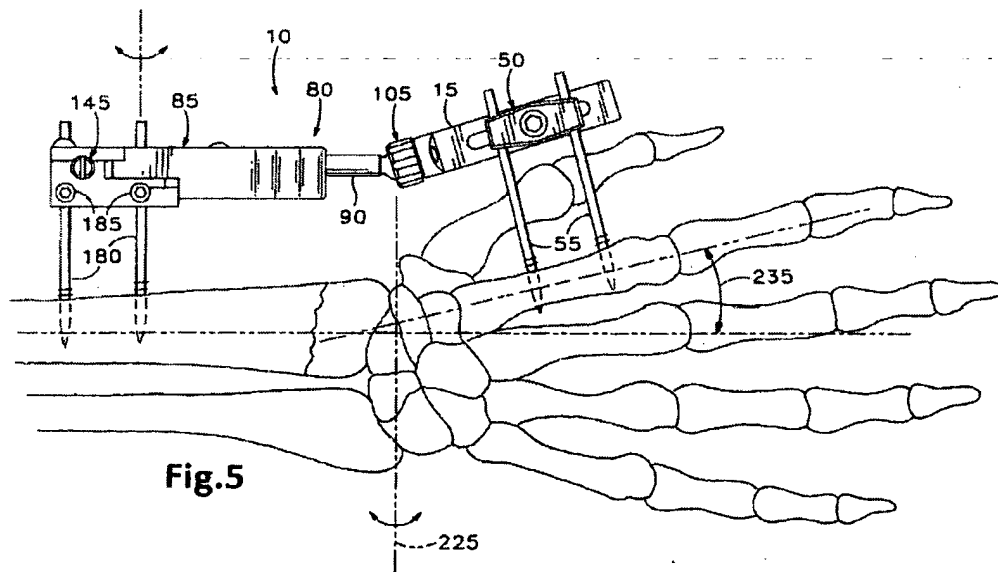
A. Claims 1-12

Independent claim 1 was rejected as being anticipated by Huebner. However, claim 1 has been amended as follows:

1. (Currently Amended) A bone plate for bone fixation, comprising:  
first and second plate members **structured to be placed under skin**  
**and** each defining one or more openings configured to receive fasteners that  
secure the first and second plate members to portions of at least one bone; and  
a joint connecting the first and second plate members and defining an  
angular disposition between the first and second plate members, the joint having  
(1) a pivotable configuration in which the angular disposition is adjustable by  
pivotal movement of the first plate member about two or more nonparallel axes,  
and (2) a fixed configuration in which the angular disposition is fixed.

Support for this amendment to claim 1 is inherent to the term “bone plate” and also is provided in the application, for example, on page 2, lines 11-15, and in Figures 2 and 3, among others.

Huebner does not teach or suggest “first and second plate members structured to be placed under skin,” as recited in part by amended claim 1. Instead, Huebner relates to a fixator for external use:



The Huebner patent is titled "**External** Fixator for Repairing Fractures" (emphasis added). Moreover, Huebner states that "an additional object of the present invention is to provide an external fixator" (col. 4, lines 4-5), and shows a fixator with a body that is held in a spaced relation from bone, at a significant distance from the bone and skin, by pins 55, 180.

In the Office action, the Examiner suggested that distal member 15 and medial block 85 of Huebner correspond to the recited plate members. However, neither the distal member nor the medial block of Huebner is "structured to be placed under skin," as recited by claim 1. For example, the distal member and medial block do not have a low profile or other features consistent with being structured to be placed under skin (see, for example, the subject application on page 9, lines 2-4, 11-13, and 20-22). Furthermore, it would not have been obvious to structure the external fixator of Huebner for placement under skin because this would substantially change the external fixator's principle of operation and the surgical procedure for installation.

Huebner also discloses pins 55 and 180 that penetrate the skin. However, these pins not define "one or more openings configured to receive fasteners that secure the first and second plate member to portions of at least one bone," as recited in part by claim 1.

For at least the reasons presented above, claim 1 should be allowed. Claims 2-12, which depend from claim 1, also should be allowed for at least the same reasons as claim 1.

*B. Claims 13-17*

Independent claim 13 was rejected as being anticipated by Huebner, Bruchmann, and Christensen. However, claim 13 has been amended as follows:

13. (Currently Amended) A bone plate for fixation of the radius, comprising:

first and second plate members each defining one or more openings configured to receive fasteners for securing the first and second plate members to different portions of a radius bone, **at least one of the first and second plate members having a nonplanar inner surface that is generally complementary to a ~~being contoured to fit onto~~ distal surface region[[s]] of the radius bone, such that the at least one plate member fits onto the radius bone;** and

a joint connecting the first and second plate members and defining an angular disposition between the first and second plate members, the joint having an adjustable configuration in which the angular disposition is adjustable and a fixed configuration in which the angular disposition is fixed.

Support for the amendments to claim 13 are provided in the application, for example, in Figure 19, on pg. 11, lines 16-17, and on pg. 34, line 22, to pg. 35, line 1, among others.

None of the three cited references, alone or in combination, teaches or suggests at least one plate member “having a nonplanar inner surface that is generally complementary to a distal surface region of the radius bone,” as recited in part by amended claim 13.

Huebner relates to an external fixator that is spaced from bone, as described above in relation to claim 1. Accordingly, Huebner does not teach or suggest any correspondence between surface regions of plate members and bone, much less the recited complementarity. Therefore, for at least this reason, Huebner does not anticipate amended claim 13.

Bruchmann relates to an external tutor for treating radius fractures. Figures 1 and 3 below show views of the tutor from above and from the side, respectively. The tutor is configured to be spaced from bone. Accordingly, Bruchmann does not teach or suggest any correspondence between surface regions of plate members and bone, much less

the recited complementarity. Therefore, for at least this reason, Bruchmann does not anticipate amended claim 13.

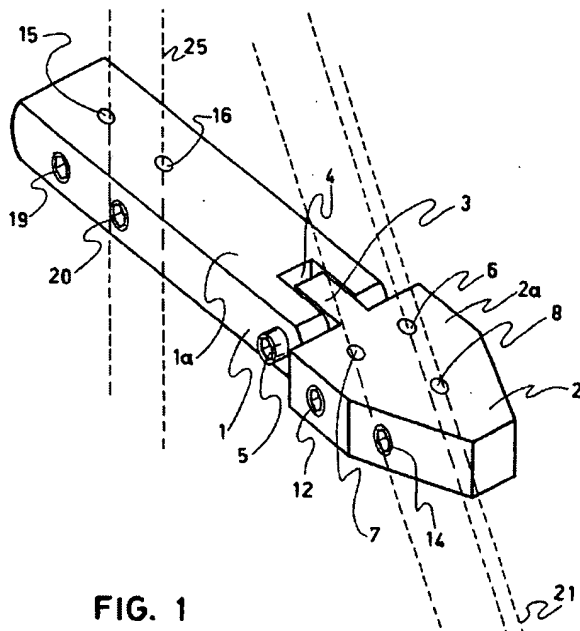


FIG. 1

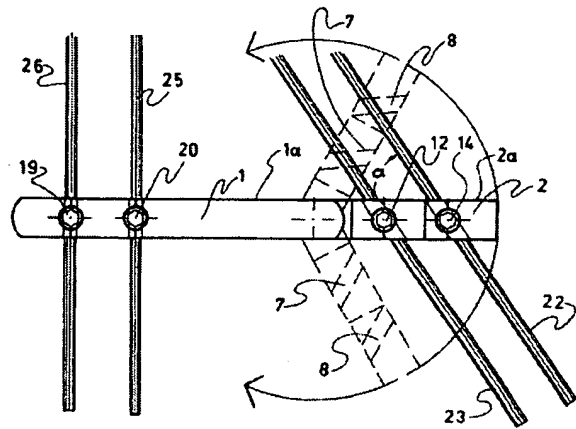
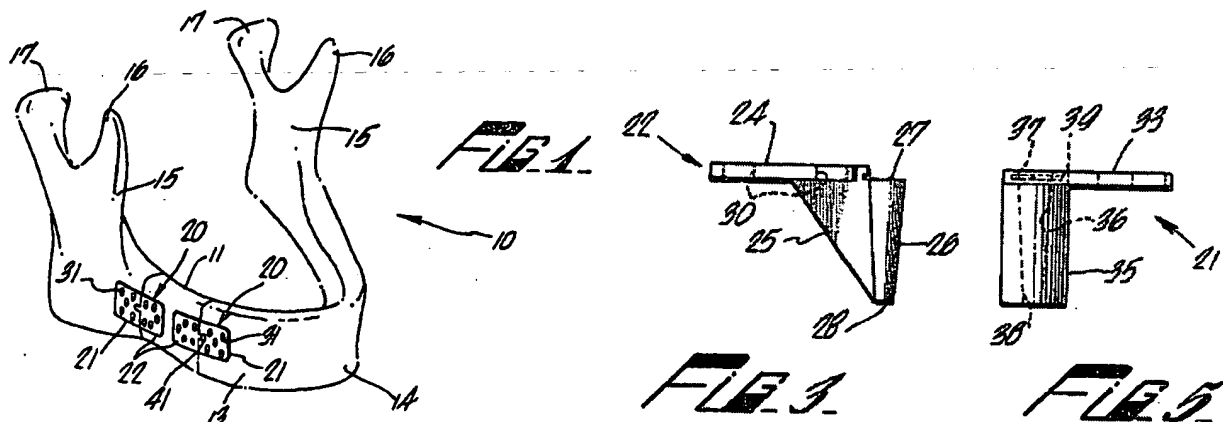


FIG. 3

Christensen relates to a prosthetic appliance for use in anchoring bone grafts or replacing sections of bone. Figure 1 of Christensen shows an embodiment 20 of the appliance attached to a human mandible 10:



Figures 3 and 5, respectively, show side views of a male coupler 22 and a female coupler 21 of the appliance. Each coupler has an anchor plate 24 or 33 that is disposed adjacent a surface of bone. Each anchor plate has a planar inner surface. The

Examiner supported this assertion in the Office action by stating that “the Christensen bone plates are contoured for placement onto distal surface regions of the radius bone which include flat regions.” Accordingly, Christensen does not teach or suggest at least one plate member “having a nonplanar inner surface,” as recited in part by amended claim 13. Therefore, Christensen does not anticipate claim 13.

Applicants assert that it would not have been obvious to modify the appliance of Christensen to produce the bone plate of claim 13. However, in the Office action, the Examiner suggested that it would have been obvious to modify the appliance of Christensen for use on the radius bone. In particular, the Examiner rejected claim 15 as being obvious over Christensen in view of Esser.

The Examiner asserted that Christensen characterizes the disclosed apparatus as being flexible and easy to use in other parts of the body. However, applicants contend that this flexibility is due to the apparatus having planar anchor plates and thus not being contoured for use on any particular bone region.

Esser discloses bone plates for fixation of complex fractures of the distal radius. The bone plates are designed to serve as templates for reconstruction of fractured bone. For example, Esser states that “the bone plate is pre-shaped to match the contour of the anatomic shape of an unfractured distal radius to assist in reduction of complicated fractures” (col. 3, lines 7-9).

It would not have been obvious to combine the pre-shaped bone plate of Esser with the jointed appliance of Christensen. Introduction of an adjustable joint into the bone plate of Esser would have allowed the shape of Esser’s bone plate to be changed to a range of non-anatomical configurations. In these non-anatomical configurations, the

plate would not have matched the anatomical shape of an unfractured distal radius, contradicting a stated goal of Esser. At the time of the invention, the movable joint of Christensen would have been considered to be an unnecessary addition to the plate of Esser (and pre-shaped bone plates in general), which would increase the complexity of the plate, apparently without improving its templating ability during fracture reduction.

However, applicants have disclosed a rationale for adding a joint to a pre-shaped bone plate, as an aid to fracture reduction after attachment of the plate. This rationale is neither taught nor suggested by the prior art and thus the prior art lacks any motivation for the claimed invention. Therefore, claim 13 should be allowed. Claims 14-17, which depend from claim 13, also should be allowed for at least the same reasons as claim 13.

*C. Claims 18-24*

Independent claim 18 was rejected as being anticipated by Huebner. However, claim 18 has been amended as follows:

18. (Currently Amended) A bone plate for bone fixation, comprising:  
first and second portions **structured to be placed under skin, each portion defining at least one opening for receipt of a fastener that secures the portion** ~~configured to be secured~~ to at least one bone; and  
a joint connecting the first and second portions and defining an angular disposition between the first and second portions, the joint having (1) an adjustable configuration in which the angular disposition is adjustable by pivotal movement of the first portion relative to the second portion about three orthogonal axes and (2) a fixed configuration in which the angular disposition is fixed.

Support for the amendment to claim 18 is inherent to the term “bone plate” and also is provided in the application, for example, on page 2, lines 11-15, and in Figures 2 and 3, among others.



Huebner does not teach or suggest “first and second portions structured to be placed under skin, each portion defining at least one opening for receipt of a fastener,” as recited in part by amended claim 18. Support for this assertion is presented above in relation to claim 1. Accordingly, claim 18 should be allowed. Claims 19-24, which depend from claim 18, also should be allowed for at least the same reasons as claim 18.

*D. Claims 40-53*

Independent claim 40 was rejected as being anticipated by Huebner. However, claim 40 has been amended as follows:

40. (Currently Amended) A bone plate for bone fixation, comprising:  
first and second plate members **structured to be placed under skin**  
**and** each defining one or more openings configured to receive fasteners that secure the first and second plate members to portions of at least one bone; and  
a joint connecting the first and second plate members and defining a relative angular disposition of the first and second plate members, the joint having (1) an adjustable configuration in which the relative angular disposition is adjustable by movement of at least one of the first and second plate members about two or more nonparallel axes, and (2) a fixed configuration in which the relative angular disposition is fixed.

Support for the amendment to claim 40 is inherent to the term “bone plate” and also is provided in the application, for example, on page 2, lines 11-15, and in Figures 2 and 3, among others.

Huebner does not teach or suggest “first and second plate members structured to be placed under skin,” as recited in part by amended claim 40. Support for this assertion is presented above in relation to claim 1. Therefore, for at least this reason, claim 40 should be allowed. Claims 41-53, which depend from claim 40, also should be allowed for at least the same reasons as claim 40.

**IV. Double Patenting**

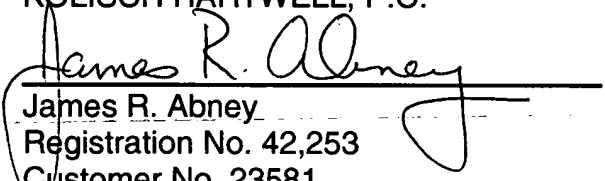
Claims 1-4, 6-7, 12-20, 24, 39-43, 45, 46, and 51-53 were rejected provisionally for obviousness-type double patenting over claim 4 or claim 7 of copending U.S. Patent Application Serial No. 10/717,399 ('399) in view of Huebner. However, applicants have amended claims 1, 13, 15, 18, and 40, and have canceled claim 39. Accordingly, the rejections for double-patenting should be moot.

**V. Conclusion**

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

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Lisa Holstein